



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,789	11/12/2003	Hallett H. Mathews	4002-3449/PC466.02	7185
7590	06/10/2005		EXAMINER	
Woodard, Emhardt, Moriarty, McNett & Henry LLP Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137			BLANCO, JAVIER G	
		ART UNIT	PAPER NUMBER	3738
DATE MAILED: 06/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/706,789	MATHEWS, HALLETT H.
	Examiner	Art Unit
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 May 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 37-43 and 48-85 is/are pending in the application.
 4a) Of the above claim(s) 39-43, 52-55 and 57-85 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 37, 38, 48-51 and 56 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I (claims 37-56) in the reply filed on May 31, 2005 is acknowledged. The traversal is on the ground(s) that "searching and examining the entire application can be made without serious burden". This is not found persuasive because the spinal prosthesis art (class 623/17.16) is a crowded art. The spinal positioner/stabilizer art (606/61) is also a crowded art. As indicated in the restriction requirement, both sets of claims have different classification, and will require different searches. This shows that there is a serious burden on the Examiner. The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of Species F (Figures 15a-15c) in the reply filed on May 31, 2005 is acknowledged. The traversal is on the ground(s) that "examination of the claims with reference to all of the disclosed embodiments would not be burdensome, and would promote efficiency". This is not found persuasive because, as defined in MPEP 808.01(a), for an Election of Species "*it is not necessary to show a separate status in the art or separate classification*". Also, that same section of the MPEP teaches that for a multiplicity of species requiring extensive and/or burdensome search, "*a requirement for an election of species should be made prior to a search*". Furthermore, the Office Action state: "*should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case*". The requirement is still deemed proper and is therefore made FINAL.

2. Claims 39-43, 52-55, and 57-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 31, 2005.

Specification

3. The disclosure is objected to because of the following informality: please update the "CROSS-REFERENCE TO RELATED APPLICATION" section (i.e., now abandoned). Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 37, 38, 48-51, and 56 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Felt et al. (US 5,888,220 A; cited in Applicant's IDS).

Felt et al. disclose a spinal surgical instrument for distracting a disc space comprising: (i) a shaft (e.g., delivery cannula 10) extending between a proximal end and a distal end; and (ii) an inflatable portion (e.g., balloon 12) adjacent said distal end (see Figure 1), said inflatable portion having a reduced size configuration for insertion into the disc space (see column 3, lines 19-21;

column 5, lines 54-59) and an enlarged inflated configuration (see column 3, lines 19-21; column 5, lines 54-63), wherein when in said inflated configuration said inflatable portion defines an upper vertebral endplate contacting surface and an opposite lower vertebral endplate contacting surface (see column 5). A biomaterial is delivered in a flowable form through delivery cannula 10 and said biomaterial is curable after delivery (see column 3 and columns 5-7). Another cannula can be used to deliver biomaterial to the disc space (see column 6, lines 36-53; see entire document). A list of suitable flowable/curable biomaterials is disclosed at columns 7-9.

Felt et al. disclose at column 5, lines 21-29 the desirability of distracting the disc space to any desired final dimensions and position. Furthermore, Felt et al. disclose at column 6, lines 6-20 that the balloons can be provided in any suitable form/shape, depending on the manner in which the biomaterial is to be delivered and cured. Although Felt et al. intended purpose is to *"reconstruct the disc in a manner that more closely approximates the overall physical characteristics and relationship of the original annulus and nucleus"* (see column 6, lines 50-53), they did not particularly disclose the upper and lower vertebral endplate contacting surfaces as each having an area in the range of 0.1 square inches to 0.5 square inches. It should be noted that said area would vary depending on the degree to which the balloon is inflated. Therefore, at any given moment during inflation, the balloon will comprise an upper/lower vertebral endplate contacting area in the range of 0.1 square inches to 0.5 square inches. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the the upper and lower vertebral endplate contacting surfaces as each having an area in the range of 0.1 square inches to 0.5 square inches since it has been held that where the general conditions of

Art Unit: 3738

a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Weikel et al. (US 6,632,235 B2), and Lots et al. (US 2003/0033017 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



June 7, 2005



David H. Willse
Primary Examiner